



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

10/10/04

| | | | | |
|--|-------------|----------------------|----------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/183,375 | 10/30/1998 | JANOS SZEBENI | 003/098/SAP | 3056 |
| 7590 | 10/18/2004 | | EXAMINER | |
| THOMAS G. WISEMAN VENABLE, BAETJER, HOWARD & CIVILETTI LLP SUITE 1000 1201 NEW YORK AVENUE, N. W. WASHINGTON, DC 20005 | | | KISHORE, GOLLAMUDI S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| DATE MAILED: 10/18/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/183,375 | SZEBENI ET AL. |
| | Examiner | Art Unit |
| | Gollamudi S Kishore, Ph.D | 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 July 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4,6-11,14 and 16-21 is/are pending in the application.
 4a) Of the above claim(s) 7-9,11,18 and 19 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4,6,10,14,16,17,20 and 21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The RCE filed on 7-27-04 is acknowledged.

Claims included in the prosecution are 1-4, 6, 10, 14, 16-17 and 20-21. Claims 7-9, 11 and 18 and 19 remain withdrawn as directed to non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the parent claim 1, the amphiphilic carrier is 'polyethoxylated oil or derivatized polyethoxylated oil'. Claim 14 is inconsistent with claim 1 in that it defines the carrier as liposomes and others.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4, 6, 10, 14, 16-17 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terwogt (cancer Treatment Reviews, March 1997) or O'Brien (Annals of Oncology, 1992) in view of Ko (5,851,528).

Terwogt teaches that that the antitumor drug paclitaxel is usually administered in combination with the vehicle, cremophor EL (polyethoxylated castor oil) and the administration of this combination causes severe hypersensitivity reactions (pages 88-89). What is lacking in Terwogt is the teaching of the administration of compliment activation inhibitors.

O'Brien teaches that several cytotoxic drugs including Taxol and doxorubicin cause hypersensitivity reactions (abstract and Table 2).

Ko teaches that compliment system includes a group of proteins in blood plasma, which plays an integral role in immune and allergic reaction and discloses a method of inhibiting complement activation by administering complement activation inhibitors. The method involves the administration of the inhibitor in controlled release delivery devices such as liposomes. The method is used for various conditions including the drug induced allergies and inflammation (note the abstract, col. 3, lines 49-52, col. 5, lines 32-51, col. 11, lines 1-42, examples and claims). Ko is also suggestive of the administration of the inhibitor along with the drug from his statements on col. 10, line 42 et seq., according to which the inhibitor "can be combined with appropriate pharmaceutical formulation. Ko however, does not specifically teach instant drugs or carriers such as Cremophors.

In essence the reference of Terwogt shows the problems (hypersensitivity) associated with the commonly used drug-carrier (paclitaxel-

Cremophor) combination and that of O'Brien shows that several drugs cause allergic (hypersensitivity) reactions. The reference of Ko offers a solution.

To use compliment activation inhibitors to reduce or inhibit the hypersensitivity reactions caused by paclitaxel-cremophor EL combination or that caused by drugs such as doxorubicin and others would have been obvious to one of ordinary skill in the art since Ko teaches that such an administration would reduce the allergies and inflammation caused by the drugs. The criticality of the administration of the compliment activation inhibitor prior to the administration of the drug is unclear to the examiner since it would be obvious to one of ordinary skill in the art that such an administration would prevent the active agent or the carrier from activation of the compliment system. The criticality of the active agent in claim 17 is also unclear to the examiner since the claims are drawn to the inhibition of the hypersensitivity reactions by the compliment activation inhibitor and hemoglobin is known to be administered to anemic patients. Compliment inhibition by the inhibitor occurs irrespective of the nature of the drug.

Applicant's arguments have been fully considered, but are deemed to be moot in view of this new rejection.

The references cited are already of record.
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GSK
Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK